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April 25, 2002

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Attention: 8(e) Coordinator
U. S. Environmental Protection Agency
Document Control Officer
Office of Pollution Prevention and Toxic Substances, 7407
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Ladies and Gentlemen:

Subject: Notice in Accordance with TSCA Section 8(e) – Preliminary results from a cancer incidence study of employees assigned to a BASF Corporation former chemical manufacturing unit in Geismar, LA that ceased operations in 1987

BASF Corporation undertook a cancer incidence and mortality study in response to employee and management concerns about what appeared to be an unusual number of cancer cases occurring during the last several years among employees who had previously been assigned to a multi-step chemical manufacturing unit producing bentazon (CAS# 25057-89-0). This unit was operated only between 1979 and 1987. One objective of the study was to determine if there was a relative excess of overall or site-specific cancers among these employees based on comparisons with the cancer experience of South Louisiana residents and other employees working at the same production site. A second objective was to determine whether or not site-specific cancer occurrences were associated with longer and more direct contact with process chemicals and to assess whether or not any observed associations were possibly causal. The final manufactured product, bentazon, has been extensively tested for registration and reregistration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and is not implicated as a suspect causative agent.

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Based on review of industrial hygiene records and discussions with employees, jobs were classified as having high or low likelihood of contact with the various process chemicals. Review of exposure incidents reported to the Medical Department was also undertaken to characterize the patterns of acute exposures occurring in the unit. The most frequently reported exposures were to phosgene, dimethylcyclohexylamine (DMCA), chlorobenzene, isopropylamidosulfonylchloride (IPS) and IPS residues, thionyl chloride, sulfuric acid, sodium hydroxide, hydrochloric acid, ethylene dichloride, and anthranilic acid. These chemicals were either raw materials in the process or process intermediates. Exposure incident rates were highest during 1979 and were higher for jobs classified as having a high likelihood of contact with process chemicals.

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Previously, in 1997, BASF had filed a report with the U.S. Environmental Protection Agency (EPA) involving an epidemiologic assessment of cancer occurrences among employees assigned to same unit [BASF REG. DOC. #97/5325]. That report was prepared in response to a request for information from the EPA. It contained a summary of the mortality experience of unit employees through 1996 and a discussion of cancer cases with emphasis on two testicular cancer cases that had occurred early in the history of the unit.

We are now providing information regarding some preliminary findings from the new study. Following completion of this study, final reports will be issued describing the study methods and results and discussing the findings in detail.

Using multiple record sources, 244 employees were identified who had been assigned to the unit for 3+ months during its period of operation from 1979-87. Also identified were 855 employees to serve as internal referents. These employees had worked at the production site in other work areas during the same time period.

Among unit employees, there were 17 observed deaths compared to 23.4 expected deaths based on age- and calendar year-specific death rates for the comparable general U.S. population between 1979 – 2001. There were 7 deaths due to cancer compared to 5.8 expected deaths.

During the years of active employment (1979-2001), there were 14 observed cancer cases among unit employees compared to 8.3 expected cases based on South Louisiana age-, race- and calendar year-specific incidence rates. In the referent group, there were 30 cancer cases compared to 35.9 expected cancer cases.

Among 98 men assigned to the unit for the full year of 1979, there were 8 observed vs. 3.4 expected cancer cases. There were 9 observed vs. 5.0 expected cases among 153 employees working at least one year in jobs classified as having high potential contact with process chemicals. Among 46 men working in these same jobs for 5+ years, there were 3 observed vs. 1.7 expected cases. Thus, relatively more cancer cases occurred among employees who worked in the unit during all of 1979, who worked for 1+ years in high potential exposure jobs.

By type, the 14 observed cancers among employees working at the time of diagnosis included 4 prostate, 3 colon, 2 pancreatic, 2 testicular, and 1 each bladder, lung and brain cancer cases. The 4 prostate cancers compared to 1.05 expected cases. Louisiana Tumor

Registry data were only available up through 1997 and do not fully reflect the recent upsurge in early identification of prostate cancers through enhanced screening programs. Three of these cases occurred among persons working the full year of 1979, but only one case occurred among employees assigned to jobs with high potential contact with process chemicals for 5+ years. Only one of the colon cancer cases had worked for the full year of 1979, but all 3 cases had worked for 1+ years in jobs with high potential contact with process chemicals.

The 2 pancreatic cancers occurred among 28 employees reporting DMCA exposure incidents, but who held different jobs, one being in production and the other assigned to maintenance work. The finding is very unusual, but is based on only two cases. It was also a result of secondary analyses and hence could be a coincidental finding. Various experimental short-term predictive tests have been conducted on DMCA and the results are negative in those tests for carcinogenic potential.

The 2 testicular cancer cases were diagnosed in 1980 and 1983 shortly after the start-up of the process. Based on tumor doubling time estimates for testicular cancer, at least one of the tumors was most likely to have been present before the employee began working in the unit.

Other than the previously reported testicular cancer cases, BASF is unaware that any cancer associations have ever been reported for a similar production unit or with respect to the raw materials and chemical intermediates associated with this process.

While this information is preliminary, BASF is reporting it as required under Section 8(e) of TSCA. It is our practice and therefore our intent to notify affected BASF employees and others of this preliminary information. Please note that this letter does not contain confidential business information. Any further technical questions should be addressed either to me or directly to our Corporate Epidemiologist, Gerald Ott, Ph.D., at Mt. Olive, NJ (Telephone: 973-426-6997).

Very truly yours,

BASF CORPORATION

Edward J. Kerfoot, Ph.D.
Director, Toxicology & Product Regulations

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